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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,506	02/10/2004	Robert P. Smyj	PT-2063001	8702
23607	7590	06/21/2005	EXAMINER	
IVOR M. HUGHES, BARRISTER & SOLICITOR, PATENT & TRADEMARK AGENTS 175 COMMERCE VALLEY DRIVE WEST SUITE 200 THORNHILL, ON L3T 7P6 CANADA			HUANG, EVELYN MEI	
			ART UNIT	PAPER NUMBER
			1625	
DATE MAILED: 06/21/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/774,506

Applicant(s)

SMYJ ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 1-13 are pending.

#### *Claim Rejections - 35 USC § 112*

2. The rejection for Claims 1-13 under 35 U.S.C. 112, second paragraph is withdrawn for claims 1-8, 10-12 upon reconsideration in view of Applicant's remarks.

The rejection for claims 9, 13 is maintained for reasons of record.

Applicant maintained that 'equivalent of toluene' would be understood by a person skilled in the art to mean organic solvents that are alkylated benzenes similar to toluene, as described in 5194436.

However, in the absence of a definition of the 'equivalent' of toluene, it is unclear whether it refers to solvents with the same melting point as toluene or compounds having similar electronic configurations as toluene etc.

#### *Claim Rejections - 35 USC § 112*

3. The rejection for claims 1-9 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is replaced by the following rejection. This rejection is also applicable claims 10-13.

- a. *Nature of the invention.*

The instant invention is drawn to a process of preparing tetrahydrothieno[3,2-c]pyridine compound of formula 6 by dehydroxylating a corresponding 7-hydroxy tetrahydrothieno[3,2-c]pyridine in the presence of a iodosilane.

- b. *State of the prior art and the level of the skill in the art.*

Different processes for the preparation of tetrahydrothieno[3,2-c]pyridine compound has been described (4847265, 4529596, 4051141, 4127580, 6495691, PTO-1449). The process of 6495691 teaches the dehydroxylation of the corresponding 7-hydroxy tetrahydrothieno[3,2-c]pyridine in the presence of  $\text{SnCl}_2$ . The dehydroxylation in the presence of iodosilane has been

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described by Stoner et al (Tetrahedron. 1995, 51(41): 11043-11062, PTO-1449). TMSI is also known to react with ester, ether and carbamates (Olah, J. Org. Chem. 1979, 44(8): 1247-1251, PTO-1449),

The level of the skilled in the chemical synthetic art is high.

c. *Predictability/unpredictability of the art.*

Unlike the mechanical art, the high degree of unpredictability is well recognized in the chemical synthetic art. A change in the reaction conditions, or a slight modification of the structure of the reactants may drastically affect the rate and efficacy of the reaction. For the dehydroxylation reaction in the presence of TMSI, the rate of addition and reaction temperature are crucial to obtaining acceptable yields of product (Stoner et al. page 11049, second paragraph). Deleterious effects on the rate and efficiency of the reaction have been observed when the amount of TMSI is below certain critical concentration (Stoner et al. page 11046).

d. *Amount of guidance/working examples.*

The preparation of example compounds is limited to methyl-4,5,6,7 tetrahydrothieno[3,2-c]pyridiyl-o-chlorophenylacetate in the presence of TMSI. Furthermore, the amount TMSI used in the dehydroxylation is not described in the specification either generically or specifically in the examples.

Starting materials, especially those wherein R1 and R2 are part of a heterocyclic structure, iodosilanes or chlorosilanes wherein R3 or R4 are combinations of alkyl, alkenyl, alkynyl and aromatic groups, which are not fully described in the specification, are not seen but required. Sources are particularly pertinent especially when the structures of these compounds are not described. Absent sources, the public is offered mere language, rather than enablement. Ex parte Moersch 104 USPQ 122. In re Howarthe 210 USPQ 689.

e. *The breadth of the claims.*

Applicant's assertion that any concentration of iodosilane would be effective, and that the process is applicable for all the structurally diverse compounds of formula 6 (especially those wherein X is aryloxy carbonyl, or X is carbamoyl wherein R1 and R2 are part of a heterocyclic structure, or Z is aryloxy), does not commensurate with the scope of the objective enablement, especially in view of the high degree of unpredictability in the art and the limited working

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examples, and the fact that the amount of iodosilane used is critical to the dehydroxylation reaction (paragraphs c, d above).

f. *Quantitation of undue experimentation.*

Since insufficient teaching and guidance have been provided in the disclosure (paragraphs c-e above), one of ordinary skill in the art, even with high degree of skill, would not be able to make and use all the compounds as claimed without undue experimentation, especially when the concentration of iodosilane critical for the dehydroxylation reaction is not described in the specification (see paragraph 4 below).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The concentration of iodosilane for the dehydroxylation reaction, which is critical for the rate and efficiency of the instant process, is not described in the specification.

***Conclusion***

5. Horne (6495691, PTO-1449) only teaches the dehydroxylation reaction in the presence of  $\text{SnCl}_2/\text{HCl}$  (Scheme 7).

Stoner (Tetrahedron. 1995, 51(41): 11043-11062, PTO-1449) teaches the dehydroxylation of biarylmethanols in the presence of TMSI. However, TMSI is also known to react with ester group (Olah, J. Org. Chem. 1979, 44(8): 1247-1251, PTO-1449), thereby

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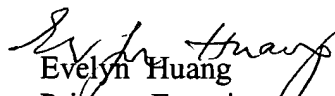
teaching away from the instant process for making the instant compound having a carboxyl or alkyloxycarbonyl moiety.

Absent is the motivation to modify the prior art process, alone or in combination, to arrive at the instant invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Evelyn Huang  
Primary Examiner  
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